



News Release

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NeuroStar TMS Therapy Shows Promise as Effective Once-Monthly Maintenance Therapy in Patients with Major Depressive Disorder

Pilot Study Reveals a Majority of Medication-Free Patients Treated with NeuroStar TMS Experienced Remission After Six Weeks with Durable Effects through Three Months

NEW YORK, May 5, 2014 – Neuronetics, Inc. announced today results from a new, dual-arm randomized pilot study that showed a trend toward symptomatic improvements with once-monthly TMS maintenance therapy in medication-free patients treated with NeuroStar TMS Therapy® for Major Depressive Disorder (MDD). Six weeks of acute NeuroStar TMS Therapy induced remission in 61.2 percent of all enrolled patients. At three months, 62.5 percent of medication-free patients randomized to once-monthly treatment with NeuroStar TMS Therapy maintained response as compared to 43.8 percent of patients who did not receive maintenance treatment. The complete findings will be presented at the 167th American Psychiatric Association Annual Meeting in New York City.

“This pilot study supports the notion that maintenance TMS may be useful in the prevention of recurrence of major depression and is an important step in learning what the optimum treatment parameters will be,” said Scott Aaronson, M.D., Director of Clinical Research Programs, and Associate Medical Director at Sheppard Pratt. “This preliminary information will help define an approach to TMS as a maintenance therapy as we extend our understanding of the long-term usefulness of TMS in the treatment of people with this debilitating illness.”

In the study, medication-free patients with a diagnosis of unipolar, non-psychotic MDD, who had failed to receive benefit from prior antidepressant medication were treated with 6 weeks of NeuroStar TMS Therapy; patients who met response criteria were randomized to either once

monthly maintenance TMS treatments or monthly observation. Patients in either cohort could receive TMS reintroduction for protocol-defined symptomatic worsening. The primary outcome was the proportion of patients without symptomatic worsening throughout the three months of the maintenance treatment phase.

“As evidenced by this first pharmacotherapy-free maintenance trial, Neuronetics is committed to investing in continued research efforts that provide validation of NeuroStar TMS Therapy, and which may help better our understanding of depression and improve patients’ therapeutic outcomes,” said David Brock, M.D, Medical Director at Neuronetics.

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About NeuroStar TMS Therapy®

Neuronetics’ NeuroStar TMS Therapy System was the first TMS system cleared by the FDA in the United States for the treatment of Major Depressive Disorder (MDD). The NeuroStar TMS Therapy System is indicated for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. NeuroStar TMS Therapy is a non-systemic (does not circulate in the bloodstream throughout the body) and non-invasive (does not involve surgery) form of neuromodulation. It stimulates nerve cells in the brain by delivering highly-focused MRI-strength magnetic field pulses which lead to activation of cortical and deep brain structures known to be involved in mood regulation. The treatment is available by prescription and typically administered daily for 4-6 weeks.

For full safety and prescribing information, visit www.NeuroStar.com.

About Depression

Major depressive disorder is one of the most common mental disorders in the United States. It affects about 25 million Americans, and it’s estimated that about four million patients do not benefit from standard treatments for depression, even after repeated treatment attempts. People with depression may experience a range of physically and emotionally debilitating symptoms, including anxiousness, sadness, irritability, fatigue, changes in sleep patterns, loss of interest in previously enjoyable activities and digestive problems.

About the Study

Patients with a diagnosis of unipolar, non-psychotic MDD, who had failed to receive benefit from prior antidepressant treatment, participated in a randomized, open-label, multisite trial. Sixty-seven medication-free patients who responded after 6 weeks of medication-free Neurostar TMS Therapy, were randomized to one of two study arms: once-monthly maintenance TMS treatments (arm A) or monthly observation (arm B). Patients in either arm could receive a TMS reintroduction course for protocol-defined symptomatic worsening. The primary outcome was the proportion of patients without symptomatic worsening throughout the three months of the maintenance treatment phase.

Of the 67 medication-free patients enrolled, 49 patients were randomized (23 to arm A and 26 to arm B); 32 patients (16 arm A, 16 arm B) met evaluable criteria at 21 weeks. Forty-one of 67

patients met remission criteria at the end of acute treatment (61.2 percent). At three months, 10 out of 16 patients in arm A (62.5 percent) versus seven out of 16 patients in arm B (43.8 percent) did not experience symptomatic worsening. At six months, 15 out of 16 patients in arm A vs. eight out of 16 patients in arm B remained in the study.

About Neuronetics

Neuronetics, Inc. is a privately-held medical device company focused on developing non-invasive therapies for psychiatric and neurological disorders using MRI-strength magnetic field pulses. Based in Malvern, PA, Neuronetics is the leader in the development of TMS Therapy, a non-invasive form of neuromodulation. For more information, please visit www.neuronetics.com or www.neurostar.com.

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